

Remarks

Applicants note that all amendments, cancellations, and additions of Claims presented herein are made without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG),¹ and without waiving the right to prosecute the cancelled claims (or similar claims) in the future.

The Examiner has indicated that the benefit claim in the preliminary amendment filed 1/11/02 does not comply with the relevant statute and patent regulations (Office Action, pg. 2). The Applicants submit herewith a petition and fee to correct the priority claim. As such, the Applicants request that the objection be withdrawn.

The Examiner has indicated that the application is not in compliance with the sequence rules (Office Action, pg. 4). The Applicants have amended the specification to include sequence identifiers where needed. As such, the Applicants respectfully request that the objection be withdrawn.

The Examiner has indicated that should Claim 11 be found allowable, Claim 12 will be objected to as being a substantial duplicate thereof (Office Action, pg. 13). The Applicants have canceled Claim 12 (while reserving the right to prosecute the canceled claim or a similar claim in the future). As such, the objection is moot.

In the Office Action dated 1/11/05, the Examiner issued several rejections. Each of the rejections is listed below in the order in which they are herein addressed.

- I) Claims 3, 4, 7, 8, 11, 12, 15, and 16 are rejected under 35 U.S.C. 112, first paragraph as allegedly lacking written description;
- II) Claims 3, 4, 7, 8, 11, 12, 15, and 16 are rejected under 35 U.S.C. 112, first paragraph as allegedly lacking enablement; and
- III) Claims 3, 4, 7, 8, 15 and 16 are rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite.

¹ 65 Fed. Reg. 54603 (Sept., 8, 2000).

I) The Claims are supported by adequate written description

The Examiner has rejected Claims 3, 4, 7, 8, 11, 12, 15, and 16 under 35 U.S.C. 112, first paragraph as allegedly lacking written description (Office Action, pg. 5). In particular, the Examiner states:

"the claims are directed to or encompass a genus of fusion proteins comprising a single amino acid of Smad3 and a genus of fusion proteins comprising a single amino acids of FAST-1. The specification and claim do not place any limit on the number of amino acid substitutions, deletions, insertions and/or additions that may be made to a Smad3 or FAST-1 polypeptide." (Office Action, pg. 7).

The Applicants respectfully disagree. Nonetheless, in order to further the business interests of the Applicants and while reserving the right to prosecute the original (or similar) claims in the future, the Applicants have amended Claims 3, 4, 7, 8, 11, 12, 15, and 16 to refer to specific Smad3 and FAST-1 polypeptides by SEQ ID NO. As such, the Applicants submit that the claims provide adequate written description for the claimed subjects matter. Thus, the applicants respectfully request that the rejection be withdrawn.

II) The Claims are Enabled

The Examiner has rejected Claims 3, 4, 7, 8, 11, 12, 15, and 16 under 35 U.S.C. 112, first paragraph as allegedly lacking enablement (Office Action, pg. 7). The Applicants respectfully disagree with the rejection. In particular, the Examiner states "However, the claims do not require that the fragment of Smad3 interact with the fragment of FAST-1 and thus recruit the Smad3/FAST-1 complex to the reporter DNA or a site operably linked to the reporter gene, such that reporter gene transcription is stimulated." (Office Action, pg. 8). The Applicants respectfully disagree. Nonetheless, in order to further the business interests of the Applicants and while reserving the right to prosecute the original (or similar) claims in the future, the Applicants have amended Claims 3, 4, 7, 8, 15, and 16 to include the element of the FAST-1 and Smad3 polypeptides interacting and stimulating reporter gene expression.

The Examiner further states "The claims do not require that the "gene activating moiety" activate reporter gene expression in the reporter gene assay." Office Action, pg. 8. The Applicants respectfully disagree. Nonetheless, in order to further the business

interests of the Applicants and while reserving the right to prosecute the original (or similar) claims in the future, the Applicants have amended Claims 3, 4, 15, and 16 to include the element of the stimulation of reporter gene expression.

The Examiner also states "the claims do not require comparing reporter gene expression in the presence and absence of the test compound." (Office Action, pg. 9). The Applicants respectfully disagree. Nonetheless, in order to further the business interests of the Applicants and while reserving the right to prosecute the original (or similar) claims in the future, the Applicants have amended Claims 3, 4, 15, and 16 to include the element of measuring a change in the level of reporter gene expression in the presence of the test compound. As such, the Applicants submit that the claims are enabled.

The Applicants submit that the "2-hybrid" interaction assay was well known in the art at the time of the filing of the present application. In addition, the Applicants have provided working examples of 2-hybrid assays in the specification (See e.g., pages 40-44). As such, the Applicants submit that the presently claimed invention is enabled.

Finally, the Examiner states "the claims are directed to or encompass a genus of fusion proteins comprising a single amino acids of Smad3 and a genus of fusion proteins comprising a single amino acid of FAST-1." Office Action, pg. 10. As described above, the Applicants have amended the claims to be directed towards specific FAST-1 and Smad3 polypeptide sequences. As such, the rejection is moot.

Applicants note that Claims 11 and 12 do not require reporter gene expression and thus are improperly included in the enablement rejection as the Examiner has admitted "the specification, while being enabling for a method of screening for compounds that disrupt the interaction of fragment of a vertebrate FAST-1 with a vertebrate Smad3..." (Office Action, pg. 7).

The Applicants respectfully submit that the presently claimed invention is enabled. Thus, the rejection should be withdrawn.

III) The Claims are Definite

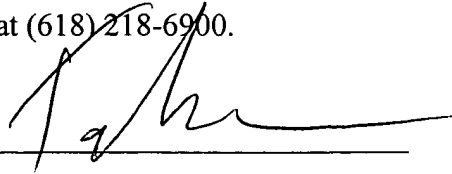
The Examiner has rejected Claims 3, 4, 7, 8, 15 and 16 under 35 U.S.C. 112, second paragraph, as allegedly being indefinite (Office Action, pg. 12). In particular, the

Examiner states "Because the instant specification does not identify that material element or combination of elements which is unique to, and, therefore, definitive of "gene activating moiety" an artisan cannot determine what additional or material limitations are placed upon a claim by the presence of this element." (Office Action, pg. 12). The Applicants respectfully disagree. The Applicants submit that the yeast 2-hybrid assay described by the claims was well known in the art at the time of the filing of the instant application. Furthermore, the specification both teaches, and provides working examples of the yeast 2-hybrid assay in operable. For example, the specification, on page 20, line 16, describes a "GAL4 activation domain," which is an example of a gene activating moiety. The Applicants submit that the meaning of the claim term is definite. As such, the Applicants respectfully request that the rejection be withdrawn.

CONCLUSION

If a telephone interview would aid in the prosecution of this application, the Examiner is encouraged to call the undersigned collect at (618) 218-6900.

Dated: 4/29/05



Tanya A. Arenson
Registration No. 47,391

MEDLEN & CARROLL, LLP
101 Howard Street, Suite 350
San Francisco, California 94105
(608) 218-6900